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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,838	07/30/2003	Susumu Satomi	SATOMI 1A	7270

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,838

Applicant(s)

SATOMI ET AL.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims for Different Invention Added After the restriction requirement

1. Newly submitted claims 26-35 are directed to an invention that is independent or distinct from the invention originally claimed invention in which the restriction requirement mailed August 18, 2006 is based upon.

It is noted that applicant originally has received a restriction requirement based on the originally filed claims which are drawn to (I) a process of using (a method of treating hepatic disease or improving liver function with valine, claims 1-11 and 22-24) and (II) a product (a kit comprising kit, claims 12-21 and 25).

The subject matter of the newly added claims does not fall into the group of the invention in which the restriction requirement is relied upon. The serum albumin level is currently utilized as the marker of the liver function test or the marker for assessing nutritional status of individuals, and there is no evidence from the prior art that the improvement of low serum albumin level would provide therapeutic utility in the treatment of hepatic disease or improve liver function. The search of either hepatic disease therapy or improvement of liver function would not reveal the subject matter of the treatment or improvement of hypoalbuminemia.

As discussed above, one practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent.

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2. Acknowledgement is made of the applicant election with the Group I invention along with hypoalbuminemia as the elected species. However, as discussed above, the newly added claims drawn to a method of treating or improving a low albumin level is independent or distinct from the original Group I invention. Accordingly, the amendment filed on September 18, 2006 is considered non-responsive.

Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

3. Upon further consideration, the examiner issues further restriction on Group I invention as followings.

Restriction to one of the following invention is required under 35 USC 121.

I(a). Claims 1, 4-6 and 22-24, drawn to a method of treating hepatic disease.

I(b). Claims 1-3 and 7-11, drawn to a method of improving liver function.

I(c). Claims 26-35, drawn to a method of treating or improving a low albumin level.

Inventions I(a)-I(c) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case invention I(a) can be practiced with different modes of operation or different functions, for example by ameliorating liver protein metabolism (e.g., US 4942172), by

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enhancing the regeneration of liver tissue (e.g., US 5196437) and by modulating immune function (e.g., US 5672605).

Furthermore, Inventions I(b) and I(c) are unrelated. In the instant case the different inventions have different effects as reasoned above. Each of the above inventions I(b) and I(c) is drawn to the treatment of totally different conditions and would appear to seek results that differ depending on what diseases or conditions is being treated.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent.

Because these inventions are distinct for the reasons given above and the search required for Group I(a) is not required for Group I(b) or I(c), restriction for examination purposes as indicated is proper.

4. In addition, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, for example hepatitis from the hepatic disease under the instant claims of the elected Group. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

With the election of a specific exemplified compound, a generic concept will be identified by the examiner as the inventive group for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call was made to Anne M. Kornbau on October 30, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614

